No. 84-1379

(16)

Supreme Court, U.S.
FILED
AUG 30 1985
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

EUGENE F. DIAMOND, et al.,

Appellants,

—v.—

ALLAN G. CHARLES, et al.,

Appellees.

ON APPEAL FROM THE UNITED STATES COURT
OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF OF *AMICI CURIAE* PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION, INC., THE CENTER FOR POPULATION OPTIONS, THE AMERICAN JEWISH COMMITTEE, NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN FAMILY PLANNING, THE NATIONAL BOARD OF THE YOUNG WOMEN'S CHRISTIAN ASSOCIATION OF THE U.S.A., NATIONAL ABORTION FEDERATION, ASSOCIATION OF PLANNED PARENTHOOD PROFESSIONALS, INC., PHYSICIANS FOR CHOICE, THE AMERICAN JEWISH CONGRESS AND INDIVIDUAL PROFESSORS, PHYSICIANS AND MEDICAL SCHOOL DEANS IN SUPPORT OF APPELLEES

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INTEREST OF AMICI*

Planned Parenthood Federation of America, Inc. (PPFA) is a not-for-profit corporation organized in 1922. PPFA is the leading national voluntary public health organization in the field of family planning with 186 affiliates in 44 states and the District of Columbia operating approximately 761 family planning clinics. Forty-four affiliates provide abortion services and most of the affiliates which do not perform abortions offer pregnancy counseling and referral.

The American Public Health Association (APHA) is a national nongovernmental organization. With a membership of over 50,000, it is the largest public health organization in the world. At its national conventions, APHA has repeatedly stated its support for legalized abortion.

The National Family Planning and Reproductive Health Association, Inc. (NFPRHA) is a national organization composed of providers and consumers of family planning and reproductive health care services under the federal Title X family planning program. It is devoted to the improvement of family planning throughout the United States.

The Center for Population Options (CPO) is a national organization concerned with the prevention of unintended adolescent pregnancy. CPO believes that the adolescent's option as to whether or not to have an abortion must be maintained.

The American Jewish Committee (AJC), a national organization dedicated to the protection of civil and religious rights, supports access to abortion as part of its traditional concern for individual liberty, privacy, and free choice.

National Association of Nurse Practitioners in Family Planning (NANPFP) is a national non-profit membership organiza-

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* All parties have given their consent to the filing of this brief in letters filed with the Clerk of this Court.

tion of professional nurse practitioners. The aim of the organization is to assure accessible quality family planning services which guarantee reproductive freedom to all.

The National Board of the Young Women's Christian Association of the U.S.A. (YWCA) represents over two million women and girls. The YWCA, a non-profit organization, has had a policy since 1967 of supporting a woman's right to choose whether or not to have an abortion, uncoerced by government.

National Abortion Federation (NAF) is a national, professional organization composed of abortion providers, individuals, and organizations active in the reproductive health care field. NAF is committed to making abortion services safe and accessible for all women.

Association of Planned Parenthood Professionals, Inc. (APPP) is a New York not-for-profit corporation whose members are physicians and health professionals associated with family planning.

Physicians for Choice, a project of PPFA, is a nationwide, bipartisan organization of 4,000 physicians which supports family planning issues and believes in preserving the right of women to decide when or whether to bear a child.

The American Jewish Congress is a national organization of American Jews. It neither favors nor opposes abortion but believes that a woman's decision whether to undergo abortion must be her own, uncoerced by government.

Individual Professors, Physicians and Medical School Deans practice obstetrics and gynecology as their medical specialty or are responsible for the education of medical students and residents, some of whom are in training in the specialty of obstetrics and gynecology.

Amici submit this brief in order to demonstrate for the Court the detrimental impact the Illinois law would have on the health and welfare of women in need of abortions.

SUMMARY OF ARGUMENT

Amici submit this brief in support of Appellees.

Section 6(1) of the Illinois Abortion Law, setting a standard of care for aborting a fetus "known to be viable," is unconstitutional for two reasons. First, it requires physicians to adhere to an objective standard of viability, in violation of the holdings of this Court that physicians must be given leeway to make such judgments on a subjective basis. *Colautti v. Franklin*, 439 U.S. 379 (1979). Second, it is void for vagueness because it fails to specify what authority will set the standard against which the physician is judged.

Section 6(4) of the law, setting a standard of care for aborting "possibly viable" fetuses, is unconstitutional because it burdens the right to abortion prior to viability by making abortions costlier, less accessible and more painful and emotionally traumatic. It is also unconstitutionally vague because it fails to specify to which period in pregnancy it applies.

Sections 11(d) and 2(10) of the law, which require physicians to tell women that certain birth control methods are abortifacients, are unconstitutional because they require the rendition of non-informative, medically dubious and biased information. These provisions are also void under the Supremacy Clause because they are preempted by federal law regulating the labeling of contraceptives.

ARGUMENT

I. SECTION 6(1) OF THE ILLINOIS LAW UNCONSTITUTIONALLY RESTRICTS A WOMAN'S RIGHT TO ABORTION

Section 6(1) of the Illinois Abortion Law criminalizes the failure to use the same care in aborting a fetus which is "known to be viable" that the physician or his assistant would use in bringing a fetus to live birth. Ill. Rev. Stat. ch. 38, ¶ 81-26(1) (1983). *Amici* support the court of appeals holding that § 6(1) is unconstitutionally vague, encroaches on the exercise of the attending physician's medical judgment, and adversely impacts upon the woman's right to obtain an abortion. *Charles v. Daley*, 749 F.2d 452, 459-60 (7th Cir. 1984).

As this Court has observed, the viability determination itself is uncertain because of the number and imprecision of variables that must be considered. Moreover, different physicians equate viability with different probabilities of survival and some refuse to equate viability with any numerical probability at all. *Colautti*, 439 U.S. at 395-96. While physicians will necessarily disagree as to whether a particular fetus has reached viability, this Court has held repeatedly that "the determination of whether a particular fetus is viable is, and must be a matter for the judgment of the responsible attending physician." *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52, 64 (1976); *Colautti*, 439 U.S. at 496-97. *See also Doe v. Bolton*, 410 U.S. 179, 192 (1973). The Illinois law fails to give deference to the individual judgment of the attending physician as required by these cases.

Moreover, the statute leaves unclear exactly what authority a physician must look to in order to determine viability. Does "known to be viable" refer to some general medical standard? If not, to what standard, expert or authority does this language refer? Because the statute does not specify whose medical judgment is determinative, it is unconstitutionally vague. *Colautti*, 439 U.S. at 393-94. This is especially true where, as here,

"the uncertainty induced by the statute threatens to inhibit the exercise of constitutionally protected rights." *Id.* at 391.

There is no doubt that the Illinois statute has a chilling effect on the exercise of constitutional rights. Physicians unwilling to risk criminal sanctions will be reluctant to perform certain second trimester abortions because their judgment will be held up to scrutiny based on an unknown standard. This burden on the exercise of the physician's medical judgment places an unconstitutional obstacle in the path of women seeking abortions. *Id.*; *City of Akron v. Akron Center for Reproductive Health*, 462 U.S. 416, 427 (1983); *Charles v. Daley*, 749 F.2d at 460.

II. SECTION 6(4) OF THE ILLINOIS LAW SIGNIFICANTLY INTERFERES WITH A WOMAN'S RIGHT TO ABORTION AND IS NOT JUSTIFIED BY A COMPELLING STATE INTEREST

Section 6(4) of the Illinois law requires that a physician abort a "possibly" viable fetus in the same manner as he or she would attempt to bring such a fetus to live birth. Ill. Rev. Stat. ch. 38, ¶ 81-26(4) (1983). The law directly interferes with a woman's right to abortion in a number of significant ways. First, it forces a woman to end her pregnancy by methods which are costlier, lengthier, more painful and psychologically traumatic than those she might otherwise choose in consultation with her attending physician. Second, it visits criminal penalties on the woman's physician on the basis of criteria so vague and uncertain as to chill physicians in their willingness to perform abortions.

The Illinois law imposes these burdens solely in the interest of fetal life. Because it does so prior to viability, the point at which this Court has held that the state's interest in protecting fetal life becomes compelling, the law is unconstitutional. *Colautti*, 439 U.S. at 388-89; *Danforth*, 428 U.S. at 81-84.

A. The Illinois Law Interferes With the Right To Abortion By Requiring Abortions Which Are Costlier, Lengthier, More Painful and Psychologically Traumatic

Appellants claim that because the Illinois law does not require the physician to expose the woman to additional "medical risk," it imposes no legally significant burden on the right to abortion. Brief for Appellants at 40. This argument ignores the precedents of this Court which have viewed as burdens on the right to abortion factors other than increased medical risk, such as cost, delay, and decreased accessibility of abortion services. For example, in *Akron*, the Court ruled that a requirement of hospitalization for a second trimester abortion placed a "significant obstacle in the path of women seeking an abortion" because it would have increased the cost of the procedure and made it less accessible. 462 U.S. at 434-35. The same case struck down the enforced delay caused by a 24 hour waiting period for abortion. *Id.* at 449-51. *See also Danforth*, 428 U.S. at 75-79 (striking down ban on saline amniocentesis because it made post-first trimester abortions more difficult to obtain). The Illinois law imposes all these burdens and more.

1. *The Choice of Method*

There are three basic techniques for performing abortions in the second half of pregnancy.[1]

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1 This section of the brief assumes that the statute applies to a period of pregnancy somewhere between the 22nd and 24th weeks of gestation, the period during which sustained fetal survival apart from the mother becomes an extremely remote "possibility." The youngest reported surviving infants have been born at 23 weeks gestation. *See* Dunn & Stirrat, *Capable of Being Born Alive?*, 1 Lancet 553 (1984); *see generally* Williams *et al.*, *Fetal Growth and Perinatal Viability in California*, 59 Obstetrics and Gynecology 624 (1982). Yet, a leading obstetrics text states, "For infants as young as 23 weeks gestational age and as small as 600 grams, the mortality rate is essentially 100%." Pritchard *et al.*, Williams Obstetrics 749 (17th ed. 1985). As discussed in Part B, *infra*, however, the concept of "possibility" of viability is so vague as to be unconstitutional.

The first, known as dilatation and evacuation (D & E), is to dilate the woman's cervix and remove the products of conception with suction and instruments.[2] There is no possibility of fetal survival when this technique is used.[3] D & E is currently utilized in 20% of abortions of pregnancies of greater than 20 weeks gestation.[4]

A second method, the most common,[5] is to induce labor to expel the contents of the uterus. This may be accomplished by the intrauterine instillation of agents toxic to the fetus such as urea or hypertonic saline,[6] or by administration of chemicals such as prostaglandins which stimulate uterine contractions without harming the fetus.[7] The fetus is most likely to survive the prostaglandin abortion and least likely to survive the abortion utilizing urea.[8] The current method of choice is utilization of urea and prostaglandins in combination.[9]

A third method is hysterotomy, the surgical removal of the products of conception through an incision in the woman's

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2 *See generally* W. Hern, Abortion Practice 126 (1984).

3 Grimes, *Second Trimester Abortions in the United States*, 16 Family Planning Perspectives 260, 264 (1984).

4 Henshaw *et al.*, *A Portrait of American Women Who Obtain Abortions*, 17 Family Planning Perspectives 90, 93 Table 2 (1985).

5 *Id.*

6 Binkin *et al.*, *Urea-prostaglandin Versus Hypertonic Saline for Instillation Abortion*, 146 Am. J. Obstetrics and Gynecology 947, 950 (1983). *See generally* W. Hern, *supra* note 2, at 124.

7 Lee & Baggish, *Live Birth as a Complication of Second Trimester Abortion Induced With Intra-Amniotic Prostaglandin F_2 alpha*, 13 Advances in Planned Parenthood 7, 14 (1978).

8 Grimes, *supra* note 3, at 264.

9 *Id.* at 265.

uterus.[10] This method may result in live birth but is the most dangerous to the woman. It is, therefore, rarely used.[11]

Section 6(4)'s fetal protection mandate requires that a physician faced with this array of options favor a hysterotomy or prostaglandin-induced abortion over those methods which use agents toxic to the fetus such as saline or urea and to favor each of these methods over the D & E abortion.

While the "medical risk" provision of § 6(5) may allow the physician to rule out hysterotomy as clearly increasing medical risk to the woman, the choice among the other methods from a health viewpoint is less clear. In the second half of pregnancy, differences in maternal mortality among the methods are small.[12] There are differences in morbidity, but comparisons are complex, each method involving different types of rare serious complications.[13] Also, the safety of D & E abortions at this stage of pregnancy is related to operator skill and experience.[14] Given these varying factors and the severe criminal penalties which attend an error, the statute will clearly compel the physician to favor a labor-inducing abortion over D & E as the method least harmful to the fetus. There are a number of ways, however, in which selection of this method burdens a woman's right to abortion.

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10 Grimes & Cates, *Dilatation and Evacuation*, in Second Trimester Abortion, Perspectives After a Decade of Experience 119 (Berger *et al.* eds. 1981).

11 Grimes, *supra* note 3, at 262.

12 *Id.* at 263 Table 3.

13 *See* Kafrissen *et al.*, *Intra-amniotic Instillation of Hyperosmolar Urea and Prostaglandin F_2 alpha v. Dilatation and Evacuation*, 251 J.A.M.A. 916, 918 (1984); Binkin, *supra* note 6, at 947.

14 Kafrissen, *supra* note 13, at 919; U.S. Department of Health and Human Services, Centers for Disease Control Abortion Surveillance 1979-1980 at 14 (1983).

2. *D & E vs. Induction of Labor*

All health risks being equal, D & E has many advantages for the woman over the labor induction abortion. It is faster and less painful, entailing an operation which takes less than 20 minutes under local or general anesthesia as compared to a prolonged painful labor[15] lasting many hours.[16] An added advantage of D & E is that it may be performed on an out-patient basis, whereas instillation procedures require, at a minimum, overnight hospitalization.[17] This increases the accessibility of the procedure as the vast majority of hospitals refuse to permit any second trimester abortions;[18] it also relieves the woman of the ancillary costs of overnight hospitalization, including lost wages and child care expenses.

Labor induction abortions also tend to be more emotionally difficult for the woman, who must experience labor and delivery of a dead fetus or one that shows fleeting signs of life. Because the time of delivery is unpredictable, it frequently occurs when a physician is unavailable and/or when nursing staff is scarce. Thus, the woman may be alone during this experience.[19]

Finally, D & E abortions, whether performed on an inpatient or outpatient basis, are less expensive than instillation abor-

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15 Kafrissen, *supra* note 13, at 919.

16 Binkin *et al.*, *supra* note 6, at 948 Table II. Mean induction to abortion interval in this study was 14.2 hours for urea-prostaglandin abortions and 25.6 hours for saline abortions. *Id.*

17 Kafrissen, *supra* note 13, at 919. Fifty-eight percent of D & E abortions at 22 weeks' gestation were performed out of hospitals. Special Tabulation by the Alan Guttmacher Institute data tape compiled by the National Center for Health Statistics of the U.S. Department of Health and Human Services containing data on 300,000 abortions occurring in twelve states in 1980.

18 Only 10% of non-Catholic general hospitals perform mid-trimester abortions. Henshaw *et al.*, *Abortion Services in the United States, 1981 and 1982*, 16 Family Planning Perspectives 119, 123 (1984).

19 Rooks & Cates, *Emotional Impact of D & E vs. Instillation*, 9 Family Planning Perspectives 276, 276 (1977).

tions because they require less staff and institutional time.[20] The Illinois law allows none of these significant factors to be weighed in the woman's abortion decision.

3. *Labor Induction Methods Compared*

The preferred method of labor induction abortion is the intrauterine instillation of a solution of hyperosmolar urea and prostaglandins.[21] This method is the most toxic to the fetus of the induction methods but is also believed to be the safest for the woman.[22] Yet, apart from safety, there are other factors which lead physicians to favor this method over the saline abortion or the abortion using prostaglandins alone. Chief among these reasons is that it entails the shortest interval between instillation of the abortifacient agents and expulsion of the products of conception.[23] This shortened interval alleviates some of the psychological trauma and physical pain for the woman and lowers the cost of the procedure.[24] Yet, the Illinois law allows none of these factors to be taken into account in choosing an abortion method.

Another advantage of the urea-prostaglandin abortion is that because of the synergistic effect of the two chemicals, the level of prostaglandin can be lowered from what would be required in an abortion using only prostaglandins. This reduces

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20 Kafrissen, *supra* note 13, at 919.

21 Grimes, *supra* note 3, at 265.

22 Binkin *et al.*, *supra* note 6, at 950.

23 A large scale study showed that urea-prostaglandin abortions averaged 14.2 hours from instillation to expulsion of the fetus, while saline averaged 25.6 hours. Binkin *et al.*, *supra* note 6, at 948 Table II. Another study showed that 12 hours after the instillation of abortifacients, 21.4% of the patients receiving only urea, 47.8% of those receiving only prostaglandins and 77% of those receiving prostaglandins in combination with urea had aborted. Wilson, *Midtrimester Abortion with Urea, Prostaglandin F_2 alpha, Laminaria, and Oxytocin: A New Regimen*, 51 Obstetrics and Gynecology 699, 700-01 (1978).

24 Binkin, *et al.*, *supra* note 6, at 952.

some of the unpleasant side effects of prostaglandins, including nausea, dizziness and diarrhea.[25] Although some physicians may associate these minor side effects with increased medical risk, others may consider the association too tenuous to risk the criminal penalties of the statute.

The Illinois law also constrains the types of drugs that can be given to alleviate the pain the woman must undergo in a labor induction abortion. Physicians feel they can administer extremely effective analgesic drugs such as morphine to a woman experiencing an abortion, drugs which might be ruled out in alleviating the pain of childbirth because of adverse effects on the fetus.[26] The Illinois law would compel physicians to consider the health of the fetus in choosing pain medication, a consideration which would lead to increased pain for the woman.

The Illinois law adds to the cost of abortions in yet another way. Physicians who feel compelled to perform abortions by the method least toxic to the fetus, namely induction of labor by prostaglandin agents alone, may also feel compelled by professional ethics and fear of criminal prosecution to arrange for resuscitation and neonatal intensive care for aborted fetuses who may exhibit any sign of life.[27] In abortions utilizing prostaglandins alone, this rate can be as high as 7%.[28] Yet, live birth and viability are not equivalent[29] and the chance of such

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25 Wellman & Jacobson, *Intra-Amniotic Prostaglandin F_2 alpha and Urea for Midtrimester Abortion*, 27 Fertility and Sterility 1374, 1378 (1976); Wilson, *supra* note 23, at 701.

26 Magora *et al.*, *Epidural Morphine Analgesia in Second Trimester Induced Abortion*, 138 Am. J. Obstetrics and Gynecology 260 (1980).

27 *See, e.g.*, Lee & Baggish, *supra* note 7, at 8.

28 *See* Grimes, *supra* note 3, at 264.

29 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Report and Recommendations, Research on the Fetus 55-56 (1975).

Section 6(4) introduces a new element of vagueness and removes this discretion. It puts physicians in the position of guessing what degree of probability separates the merely "possible" from the "reasonably likely". Inevitably, the result will be that in order to avoid the severe criminal penalties imposed by the statute, physicians will err on the side of caution, giving the statute its widest possible berth. They will feel constrained, therefore, to abandon the individual judgments envisioned in *Colautti* in favor of rigid formulas based on the latest medical miracle. A report of an isolated instance of survival of an extremely premature infant will cause many physicians to apply the restrictive provision of § 6(4) to *all* pregnancies of similar gestation, or even to refuse to perform abortions past that stage of pregnancy.

Thus, the vagueness of section 6(4) straitjackets physicians in their professional judgments, thereby impeding their patients' ability to obtain abortions. This is exactly the chilling effect on constitutional rights that this Court has sought to eliminate in the abortion cases.[34] *See Danforth*, 428 U.S. at 67 n.8; *Akron*, 462 U.S. at 427; *Colautti*, 439 U.S. 379.

C. No Compelling State Interest Justifies Section 6(4)

Section 6(4) restricts abortion rights prior to viability. As such, it may be justified only if it promotes the state's interest in maternal health. *Roe v. Wade*, 410 U.S. at 164. Clearly, no maternal health interest is implicated here. The statute is therefore invalid.

Appellants ask this Court to recognize an important interest in fetal life prior to viability sufficient to justify § 6(4)'s direct restrictions on the abortion right. Brief for Appellants at 43. Such an approach was clearly rejected by this Court in *Colautti*, where it stated that "viability is the critical point" when the state's compelling interest in fetal life or health arises and

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34 The idea that vague statutes lead persons to "steer far wider of the unlawful zone" and avoid conduct which would otherwise be constitutionally protected has long been recognized by this Court. *Hoffman Estates v. Flipside*, 455 U.S. 489, 494 n.6 (1982) (quoting *Speiser v. Randall*, 357 U.S. 513, 526 (1958)).

"we have recognized no attempt to stretch the point of viability one way or the other." 439 U.S. at 389. By carving out a new, vaguely defined gray area prior to this critical point, appellants advocate just such a "stretching" of the state's power over a woman's abortion decision. *Amici* urge this Court to reject this approach and adhere to the clear precedent of its abortion decisions to date.

III. THE "ABORTIFACIENT WARNING" PROVISION OF THE ILLINOIS LAW IS UNCONSTITUTIONAL

A. The Statutory Provision Violates The Right To Privacy

The Illinois Abortion Law (§§ 11(d), 2(10)) requires physicians to describe methods of birth control that act after fertilization as "abortifacients". Ill. Rev. Stat. ch. 38, ¶¶ 81-31(d), 81-22(10) (1983).[35] This requirement is unconstitutional under the standards for informed consent laws set forth by this Court in *Akron*, 462 U.S. 416.

In *Akron*, this Court struck down a requirement that a physician recite an inflexible set of statements to every patient requesting an abortion. The Court held that the purpose of the "informed consent" script was not to inform, but to persuade the woman to withold her consent altogether because the physician was required to make misleading statements regarding the dangers of abortion and to articulate the state's theory of when life begins. *Id.* at 444-45.[36] The Illinois law suffers the

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35 Although the appellants claim that the statute does not require the physician to use any particular language, *see* Brief for Appellants at 12, the plain language of the statute indicates otherwise. Moreover, the State of Illinois is not before this Court to present its view on how the statute should be read. The court of appeals stated that, at the least, the statute requires the physician to tell the woman that certain birth control methods cause fetal death, a requirement which is no less objectionable. *Charles v. Daley*, 749 F.2d at 462.

36 The *Akron* law required the physician to tell the woman that "the unborn child is a human life from the moment of conception" and that abortion is a major surgical procedure with numerous possible complications, characterized by the Court as a " 'parade of horribles' intended to suggest that abortion is a particularly dangerous procedure." 462 U.S. at 445.

same defects. It articulates a medically dubious viewpoint, is essentially uninformative, and attempts to make the physician the mouthpiece for the state's theory of life. As such, it is pure propaganda, designed not to inform but to dissuade women from choosing certain birth control methods. It must be struck down as violative both of the standards of *Akron* and of a woman's right of access to contraceptives. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

1. *The Abortifacient Warning is not Informative.*

Appellants contend that telling women that drugs and devices which cause the demise of the fertilized egg are "abortifacients" serves to give them relevant information which is otherwise withheld by physicians. Brief for Appellants at 14. This is not true.

Millions of women in this country use methods of birth control which are believed to prevent pregnancy at least in part by interfering with the implantation of the fertilized ovum in the lining of the uterus. Chief among these are the intrauterine device (IUD) and the progestogen-only or "mini-pill". Contrary to appellants' insinuations, there is no medical conspiracy afoot to confuse or mislead women as to the way these methods work. Every woman requesting an IUD receives a brochure containing the following federally prescribed statement: "How the IUD prevents pregnancy is not completely understood. Several theories have been suggested. I.U.D.'s seem to interfere in some manner with the implantation of the fertilized egg in the lining of the uterine cavity. The IUD does not prevent ovulation." 21 C.F.R. §§ 310.502(b)(2), 801.427(b)(2) (1985) (Patient Information).[37] Similarly, every

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37 *Amicus* PPFA's patient brochure on IUDs states:

> There's no doubt that IUDs work, and work very well. Although we do not know all the ways in which an IUD works, one theory is that IUDs create a change (inflammation) in the lining of the uterus. This chronic inflammation keeps a fertilized egg from attaching itself to the lining of the uterus and starting a pregnancy. Also, the copper in a copper IUD can inactivate sperm.

(footnote continued)

package of oral contraceptives contains a pamphlet with the following statement: "the 'mini pill' contains only a progestogen. It works in part by preventing release of an egg from the ovary but also by keeping sperm from reaching the egg and by making the uterus (womb) less receptive to any fertilized egg that reaches it." 43 Fed. Reg. 4231 (1978).

The Illinois requirement, therefore, adds nothing to a woman's fund of knowledge about birth control. It merely adds the state's ideological gloss—that the mode of action of these contraceptives, in interfering with implantation, constitutes abortion—to the information she already receives in accordance with federal regulations. Clearly, the only purpose for this statement is to dissuade women from choosing these highly effective and widely used birth control methods.

2. *The Statutory Provision Requires Physicians to Impart Information Which Many View as Medically Inaccurate.*

The view that prevention of implantation of the fertilized egg constitutes an abortion is also contrary to accepted medical standards. The American College of Obstetricians and Gynecologists' glossary of terms for the field of obstetrics and gynecology defines "induced abortion" as the "deliberate interruption of pregnancy."[38] "Pregnancy" is defined as the "state of a female after conception and until termination of the gestation."[39] "Conception" is defined as "the implantation of the blastocyst. It is not synonymous with fertilization."[40] Using

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Planned Parenthood Federation of America, Understanding IUDs (revised 1985). PPFA's affiliates provide a contraceptive method to nearly 1.5 million patients each year.

See also Burnhill, *Intrauterine Contraception*, in Fertility Control 271, 280 (Corson, Derman and Tyrer eds. 1985) (physicians prescribing IUD's should verbally inform patients "that the IUD works primarily by preventing a fertilized egg from implanting").

38 Obstetric-Gynecologic Terminology 414 (E. Hughes ed. 1972)

39 *Id.* at 327.

40 *Id.* at 299.

these definitions, agents which work to prevent implantation or conception are contraceptives, not abortifacients.[41] The Illinois law, therefore, requires physicians to contravene the accepted views of their profession on this issue.

3. *The Statutory Provision Forces the Physician to Act as a Mouthpiece for the State's Theory of When Life Begins.*

The view that birth control methods which cause demise of the fertilized egg before implantation are "abortifacients" is based on the state's theory that human life and human pregnancy begin at the moment when sperm and egg unite and that, accordingly, any agent which interferes with the development of the fertilized ovum causes an abortion. As previously shown, this view is not based on medical principles; rather it is a philosophical or religious theory of when life begins. *Roe v. Wade*, 410 U.S. at 159-162. The state may not utilize such theories as the basis for intervention in the physician-patient consultation. *Akron*, 462 U.S. at 444; *Charles v. Carey*, 627 F.2d 772, 789 (7th Cir. 1980).

The Illinois law serves no purpose other than to convey to the woman the state's moral disapproval of her choice of birth control method and thus persuade her to forgo her choice. Such indoctrination of state values with no concomitant informative purpose is unconstitutional.

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41 *See also* the federally required patient package insert for diethylstilbestrol (DES), a drug which may be prescribed as a post-coital contraceptive in emergency situations such as rape. Although DES acts *after* fertilization to prevent implantation, *see* Morris & von Wagenen, *Interception: The Use of Postovulatory Estrogens to Prevent Implantation*, 115 Am. J. Obstetrics and Gynecology 101 (1973), the brochure states that "this treatment is usually effective in preventing pregnancy if used as described above. However, this drug will not cause an abortion if you are already pregnant." 21 C.F.R. § 310.501(b)(1). Thus, the federal Food and Drug Administration (FDA) subscribes to the prevailing medical view that the demise of the fertilized egg before it implants in the uterus is not an abortion.

B. The Abortifacient Warning Provision Of The Illinois Law Violates The Supremacy Clause.

Federal laws regulating the labeling of contraceptive drugs and devices preempt §§ 11(d) and 2(10) of the Illinois Abortion Law under the Supremacy Clause of the United States Constitution. Art. VI, § 2. Regulations of the IUD,[42] progestogen-only contraceptive pills[43] and diethylstilbestrol (DES),[44] promulgated under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* (amended 1984), meet the criteria for determining federal preemption.[45] First, the Medical Device Amendments of the FDCA, *id.* §§ 360c-360k, are an unambiguous declaration by Congress that it occupies the field of regulating contraceptive devices. The amendments expressly preempt state regulations of medical devices, including IUDs, which are "different from, or in addition to" Food and Drug Administration (FDA) requirements. *Id.* § 360k(a). Second, the information in the federally mandated patient package inserts for contraceptive drugs and devices directly conflicts with the requirements of the Illinois law. Compliance with both the federal and state regulations is impossible; in addition, the Illinois law frustrates the purpose of the federal laws to promote safe and effective contraceptive use through accurate labeling.

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42 21 C.F.R. §§ 310.502, 801 *et seq.* (1985).

43 43 Fed. Reg. 4224 (1978).

44 21 C.F.R. § 310.501(b).

45 *See Ray v. Atlantic Richfield*, 435 U.S. 151, 157-59 (1978) (to determine preemption, look to (1) clear federal intent to preclude state regulation; (2) actual conflict; (3) state law as obstacle to federal purpose; (4) pervasiveness of federal regulation; or (5) dominance of federal regulation) (citations omitted).

1. *The Federal Law Expressly Preempts the Illinois Statutory Provisions.*

Congress expressly maintains exclusive control over the regulation of contraceptive devices. In 1976, Congress passed the comprehensive Medical Device Amendments of the FDCA ("Amendments"), *id.* §§ 360c-360k, in response to a Senate Health Subcommittee hearing on the Dalkon Shield IUD. The Senate had concluded that federal uniform standards for the IUD could have averted the Dalkon Shield's significant health hazard to women. *See* 1976 U.S. Code Cong. & Ad. News 1070, 1071. As a result, the FDA promulgated national standards for labeling all new medical devices, including the IUD. 41 Fed. Reg. 6896 (1976) (codified at 21 C.F.R. § 801 *et seq.*). In addition, the Amendments expressly provide for the preemption of any state regulation which "relates to" the federal law and is "different from" that law. 21 U.S.C. § 360k(a).

Requiring a doctor to call an IUD an "abortifacient" "relates to" the federal regulation governing the labeling for IUDs. Both the federal and Illinois laws set forth prescribed information which must be given to each woman seeking an IUD. In particular, the federal law requires that the IUD's "mode of action" be included in both the physician and patient package insert. Similarly, the Illinois law requires that the physician use the word "abortifacient," a term describing the way certain devices allegedly work in the woman's body.

The state statute also meets the second prong of the preemption test for medical devices: the Illinois law is substantially different from the federal law governing IUDs. The FDA defines the term "different" as different in an essential way so as to interfere with the FDA requirement. 43 Fed. Reg. 18663 (1978). Under 21 C.F.R. § 801.427(b)(1), each patient label must state that the IUD interferes somehow with the implantation of the fertilized egg to prevent pregnancy.[46] By contrast, under Illinois law, the doctor must describe the IUD's mode of action as abortifacient, not as preventing pregnancy. This

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46 *See supra* text accompanying note 37.

essential difference between the state and federal regulations clearly interferes with the FDA requirement. Describing an IUD as "abortifacient" does not promote the effective use of the device. It merely confuses women who read one explanation and hear another from their doctor.[47]

2. *The Illinois Law Conflicts with Federal Regulations*

As shown above, the federal regulations governing the labeling of contraceptive devices explicitly preempt the Illinois law. The Illinois law is also implicitly preempted by federal regulations of contraceptive drugs and devices because the Illinois law conflicts with the federal regulations. This Court has held that a conflict results in preemption if compliance with both the state and federal regulation is impossible or if the state regulation "stands as an obstacle to the accomplishments and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67-68 (1941); *see Ray v. Atlantic Richfield*, 435 U.S. 151, 158 (1978). The Illinois law and the regulations promulgated under the FDCA conflict in both respects.

The clearest example of a direct conflict comes from the information contained in the federally mandated patient package insert for DES. The federal pamphlet expressly states that the drug will not cause an abortion. 21 C.F.R.

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47 The Illinois law would not be exempted from preemption under § 360k(b) of the Amendments to the FDCA. The Commissioner may grant an exemption only if the state requirement is more "stringent" than the federal law or if it is required by local conditions. The Illinois law is not more stringent in that it does not reduce or eliminate health risks. *See Commonwealth of Massachusetts. v. Hayes*, 691 F.2d 57, 63 (1st Cir. 1982). Rather, it simply adds the state's ideological gloss to the federal requirements. *See supra* p. 17.

Moreover, requiring doctors to say "abortifacient" would not serve any public health interest, especially since the package insert already explains how the IUD works. Thus, the Illinois law is not exempt from preemption. *See* 43 Fed. Reg. 18664 (1978) (codified at 21 C.F.R. § 808.20(c)(7)).

§ 310.501(b)(4).[48] By contrast, the Illinois law requires the doctor to describe DES, a drug which takes effect after fertilization, as an abortifacient. Similarly, the federal insert for IUDs states that an IUD works after fertilization to *prevent* pregnancy, *id.* § 310.502, while the Illinois law requires that it be described as an agent which aborts a fetus.[49] Compliance with both the federal and state regulations would be impossible.

Moreover, the Illinois law frustrates the FDA's stated purpose of creating a uniform system of accurate labeling of contraceptive drugs and devices. The FDA's objective in requiring oral contraceptive labeling is stated as follows: "[t]he FDA is charged with assuring that drugs are safe and effective for their intended use and that their labeling provides adequate information for such use and is not false or misleading." 43 Fed. Reg. 4223 (1978). The FDA states a similar objective for its IUD package inserts: "in the interest of safe and effective use, and prevention of misleading labeling, there is a need to establish uniform physician and patient labeling for such devices." 21 C.F.R. §§ 310.502(b), 801.427(b). Requiring doctors to call IUDs, DES and progestogen-only pills abortifacients is just the sort of misleading and inaccurate information which the federal inserts were designed to avoid.

In sum, federal laws governing the dissemination of contraceptive information explicitly and implicitly preempt the Illinois Abortion Law. Thus, §§ 11(d) and 2(10) of the Illinois Abortion Law are unconstitutional under the Supremacy Clause of the United States Constitution.

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48 *See supra* note 41.

49 *See also* 21 C.F.R. § 884.5360 ("A contraceptive intrauterine device (IUD) is a device used to prevent pregnancy.").

CONCLUSION

For all the foregoing reasons, the decision of the court of appeals should be affirmed.

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August, 1985

Amici wish to acknowledge the assistance of Jean Simons, a student at New York University School of Law, in the preparation of this brief.